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NOTICE OF ALLOWANCE AND FEE(S) DUE

20350 7590 11/12/2008 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR

12/06/2005

SAN FRANCISCO, CA 94111-3834

10/521,138

EXAMINER MEAH, MOHAMMAD Y PAPER NUMBER ARTHNIT

6771

1652 DATE MAILED: 11/12/2008

019957-015920US

APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. Karl F. Johnson

TITLE OF INVENTION: SYNTHESIS OF OLIGOSACCHARIDES, GLYCOLIPIDS, AND GLYCOPROTEINS USING BACTERIAL GLYCOSYLTRANSFERASES

APPLN, TYPE SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional NO \$1510 \$300 \$1810 02/12/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown

B. If the status above is to be removed, check box 5b on Part B -Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

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INSTRUCTIONS: This f appropriate. All further co indicated unless corrected maintenance fee notification	orm should be used for orrespondence including below or directed others.	or tran ig the l ierwise	smitting the ISSU Patent, advance or in Block 1, by (a					hould be completed where correspondence address as trate "FEE ADDRESS" for	
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SAN FRANCISC	O, CA 94111-383	1						(Depositor's name)	
				L				(Signature)	
				L				(Date)	
APPLICATION NO.	FILING DATE		:	FIRST NAMED INVENTOR	R	ATTO	RNEY DOCKET NO.	CONFIRMATION NO.	
10/521,138 TITLE OF INVENTIO GLYCOSYLTRANSFER/		OF O	LIGOSACCHARI	Karl F. Johnson DES, GLYCOLIPIDS	, AND GLYCO		9957-015920US EINS USING BAC	6771 CTERIAL	
APPLN. TYPE	SMALL ENTITY	IS	SUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSU	E FEE	TOTAL FEE(S) DUE	DATE DUE	
nonprovisional	NO		\$1510	\$300	\$0		\$1810	02/12/2009	
EXAMIN	NER		ART UNIT	CLASS-SUBCLASS	1				
MEAH, MOHA	AMMAD Y		1652	435-097000	-				
1. Change of corresponder CFR 1.363. Change of corresponder of corresponders of correspond	ndence address (or Cha 122) attached. ation (or "Fee Address" or more recent) attach D RESIDENCE DATA ss an assignee is identi in 37 CFR 3.11. Comp	nge of ' 'Indica ed. Use	Correspondence ation form of a Customer E PRINTED ON T		o 3 registered pater ively, the firm (having as a agent) and the nam orneys or agents. If e printed. (pp) patent. If an assign assignment.	memb es of u no nan	er a 2p to be is 3	ocument has been filed for	
Please check the appropria	te assignee category or	catego	ries (will not be pr	inted on the patent):	Individual 🗖 C	orporati	on or other private gro	oup entity 🗖 Government	
4a. The following fee(s) are submitted: Itsue Fee Publication Fee (No small entity discount permitted) Advance Order - # of Copies				th. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) A check is enclosed. Payment by readit and, Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Depoid Account Number (enclose an extra copy of this form).					
 Change in Entity Statu a. Applicant claims 	SMALL ENTITY statu	s. See	37 CFR I.27.	☐ b. Applicant is no lo					
NOTE: The Issue Fee and interest as shown by the re	Publication Fee (if requered of the United Sta	iired) v tes Pate	will not be accepted ent and Trademark	from anyone other than Office.	the applicant; a reg	stered	attorney or agent; or th	e assignee or other party in	
Authorized Signature _					Date				
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PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/521,138	12/06/2005 Karl F. Johnson		019957-015920US	6771		
20350 75	90 11/12/2008		EXAMINER			
TOWNSEND AT	ND TOWNSEND AN	MEAH, MOHAMMAD Y				
TWO EMBARCA	DERO CENTER	ART UNIT	PAPER NUMBER			
EIGHTH FLOOR		1652				

SAN FRANCISCO, CA 94111-3834

DATE MAILED: 11/12/2008

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 267 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 267 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 (571)-272-4200.

Application No. Applicant(s) 10/521,138 JOHNSON ET AL. Notice of Allowability Examiner Art Unit MD YOUNUS MEAH 1652 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to 8/20/08. The allowed claim(s) is/are 1-2, 4-5, 8, 31-32, 34, 36-44. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) \square All b) ☐ Some* c) ☐ None of the: 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. \(\overline{\text{ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. | Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) Interview Summary (PTO-413), Paper No./Mail Date Information Disclosure Statements (PTO/SB/08). 7. X Examiner's Amendment/Comment Paper No./Mail Date 4. T Examiner's Comment Regarding Requirement for Deposit 8. X Examiner's Statement of Reasons for Allowance of Biological Material 9. ☐ Other .

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Notice of Allowability

Claims 31-44 (subject matter of group 14) previously withdrawn from consideration as a result of a restriction requirement. Elected claims 1, 2, 4-5 and 8 are allowable. The restriction requirement between group 2 (claims, 2, 4-5) and 8) and group 14 (claims 31-32, 34, 36-44), as set forth in the Office action mailed on 10/12/2007, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim, Claims 31-32, 34, 36-44, directed to method production of fucosylated oligosaccharide and glycolipid using fucosyltransferase comprising SEQ ID NO: 4 no longer withdrawn from consideration because the claim(s) requires all the limitations of allowable claims. In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicants amendment of 8/20/2008 is acknowledged.

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2. Claims 1-2, 4-5, 8, 31-32, 34 and 36-44 are pending and under

consideration.

3. Claims 1-2, 4-5, 8, 31-32, 34 and 36-44 are allowed

4 An examiner's amendment to the record appears below:

Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the

issue fee.

Authorization for this examiner's amendment was given by Jennifer L. Wahlsten with Telephone on 10/28/2008.

EXAMINER'S AMENDMENT

Amend claims 1, 2, 8, 31 and 44 as follows:

1. (Currently Amended) A method for producing a fucosylated glycoprotein, the method comprising: contacting a recombinant fucosyltransferase protein with a mixture comprising a donor substrate comprising a GDP-fucose residue, and an acceptor substrate on a glycoprotein, wherein the acceptor substrate comprises an N-acetylglucosamine residue, under conditions where the fucosyltransferase catalyzes the transfer of the fucose residue from [a] the donor substrate to the acceptor substrate on the

glycoprotein, thereby producing a fucosylated glycoprotein, wherein the

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recombinant fucosyltransferase protein comprises a polypeptide having greater than 90% 95% identity to an the amino acid sequence of SEQ ID NO: 4.

 (Currently Amended) The method of claim 1, wherein the polypeptide comprises an <u>the</u> amino acid sequence of SEQ ID NO: 4.

8.(Currently Amended) The method of claim 1, wherein an acceptor substrate on the glycoprotein comprises Galβ,3/4GlcNAc-OR, NeuAca2,3Galβ,3/4GlcNAc-OR, wherein R is an amino acid, a saccharide, an oligosaccharide, or an aglycon a radical group having at least one carbon atom.

31. (Currently Amended) A method of making a fucosylated oligosaccharide, the method comprising: contacting the recombinant fucosyltransferase with a mixture comprising a donor substrate comprising a GDP-fucose residue, and an acceptor substrate comprising a sugar or oligosaccharide, wherein the acceptor substrate comprises an Nacetylglucosamine residue, under conditions where the fusion protein catalyzes the transfer of a fucose residue from the donor substrate to the acceptor thereby producing fucosylated oligosaccharide, substrate. а wherein the recombinant fucosyltransferase protein comprises a polypeptide having greater than 90% 95% identity to an the amino acid sequence of SEQ ID NO:4.

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44. (Currently Amended) A method for producing a fucosylated glycolipid, the method comprising: contacting the recombinant fucosyltransferase protein of with a mixture comprising a donor substrate comprising a GDP-fucose residue, and an acceptor substrate on a glycolipid, wherein the acceptor substrate comprises an N-acetylglucosamine residue, under conditions where the fucosyltransferase catalyzes the transfer of the fucose residue from the donor substrate to the acceptor substrate on the glycolipid, thereby producing a fucosylated glycolipid, wherein the recombinant fucosyltransferase protein comprises a polypeptide having greater than 90% 95% identity to an the amino acid sequence of SEQ ID NO:4.

The following is an examiner's statement of reasons for allowance:

Applicant has isolated novel fucosyltransferase protein from Helicobactor pylori comprising SEQ ID NO: 4. As such the claimed method of use of novel fucosyltransferase protein comprising SEQ ID NO: 4 is novel and non-obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NASHAAT T NASHED can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-1261.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public

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PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mohammad Younus Meah, PhD Examiner, Art Unit 1652 Recombinant Enzymes, 3C31 Remsen Bld 400 Dulany Street, Alexandria, VA 22314 Telephone: 517-272-1261

/Nashaat T. Nashed/ Supervisory Patent Examiner, Art Unit 1652